

- [71] Padkin A, Rowan K, Black N. Using high quality clinical databases to complement the results of randomised controlled trials: the case of recombinant human activated protein C. *BMJ* 2001; 323:923–6.
- [72] Edwards MB, Taylor KM. A profile of valve replacement surgery in the UK (1986–1997): a study from the UK Heart Valve Registry. *J Heart Valve Dis* 1999;8:697–701.
- [73] Ludman PF. The UK transcatheter aortic valve implantation registry; one of the suite of registries hosted by the National Institute for Cardiovascular Outcomes Research (NICOR). *Heart* 2012;98:1787–9.
- [74] Keogh B. Poly Implant Prothese (PIP) Breast Implants: Final Report of the Expert Group. London: Department of Health, 2012.
- [75] Bridgewater B, Gummer J, Walton PKH, Kinsman R. The Fourth EACTS Adult Cardiac Surgery Report 2010. Henley-on-Thames, UK: Dendrite Clinical Systems Ltd, 2010. 1010.
- [76] Data Protection Act 1998. London: Her Majesty's Stationery Office, 1998.
- [77] Department of Health, The Caldicott Committee—Chair: Dame Fiona Caldicott. Report on the review of patient-identifiable information, 1997.
- [78] The National Health Service Act 2006 (c. 41), Section 251. London: Her Majesty's Stationery Office, 2006.

European Journal of Cardio-Thoracic Surgery 44 (2013) 614–615  
doi:10.1093/ejcts/ezt083 Advance Access publication 26 February 2013

## EDITORIAL COMMENT

# Clinical registries: yes, but then appropriately!

Hendrik Tevæarai and Thierry Carrel\*

Clinic for Cardiovascular Surgery Inselspital, Berne University Hospital and University of Berne, Berne, Switzerland

\* Corresponding author. Clinic for Cardiovascular Surgery, Berne University Hospital, 3010 Berne, Switzerland. Tel: +41-31-6322111; e-mail: thierry.carrel@insel.ch (T. Carrel).

**Keywords:** Clinical registries • Randomized clinical trials • National database • Results of cardiac surgery procedures

In the last two decades, several cardiac surgical procedures have become standard, and the results can be considered good or even excellent. Yet, unless a procedure is considered 100% safe and efficient, cardiothoracic surgeons should not be satisfied with a 'good enough' mentality, but must perpetually strive for further improvement. One critical limitation in this endeavour is the assessment of the results, because a significant improvement in morbidity and mortality rates may be difficult to detect if these end-points already occur at very low rates. Randomized controlled trials (RCTs) remain the gold standard for reaching Level 1 of evidence. By carefully selecting the end-points as well as the inclusion and exclusion criteria, RCTs aim to rapidly provide solid information regarding a new therapeutic approach (percutaneous intervention, surgical procedure, device or drug performance) that may eventually be further extrapolated to a larger (or more global) population. However, results of RCTs may be biased because of the selection of 'best-performer' institutions and, therefore, that of such powerful studies may not adequately represent the average level of care. This is where registries may give a better picture of the real world: but, if poorly conducted, they may also lead to a distorted understanding of the reality. In the current issue of the *European Journal of Cardio-Thoracic Surgery*, Hickey *et al.* review various critical aspects of administering a registry [1]. The authors highlight the growing interest in registries and the potential they offer for future clinical, but also socio-economical, developments.

In its ideal form, a registry should provide enough evidence to support the development of individuals or collectivities and to reflect the changes in performances. Indeed, one critical asset of registries is the principle of reciprocity, requiring each participant to comprehensively and unreservedly include all of his/her data. In exchange, all participants should be granted access to a larger source of information, by means of which they would be

encouraged to learn from each other and to improve the quality of their own institution. The unrestricted use of these large databases will, however, remain sub-optimal as long as not all relevant data of all consecutive patients constituting the specific registry (transcatheter aortic valve implantation, coronary artery bypass grafting and others) are included. Geographically, registries should also be as broad as possible or at least be conceived so that different entities are compatible (same criteria and definitions) and can be technically merged into one larger database. Finally, registries should allow for longitudinal analysis in order to provide results over the long-term [2, 3].

To achieve this ambitious but inevitable objective, critical rules must be discussed, accepted and sooner or later implemented. Some already exist and are obligatory, such as the legal and ethical structures (which may vary from country to country), and others are suggested by guidelines or recommendations, such as the way data should be managed, but several are yet to be clarified. Among them, the quality of the 'raw data' is probably the most critical issue. Currently, and with only few exceptions, submission of data is facultative, and data are not subjected to obligatory third-party checks (independent audits). Inconsistencies, missing information, duplication or transcription errors, among others, can be checked and corrected after they have been submitted to the registry; however, the truth behind submitted data remains, for most centres, a matter of trust. One major exception—as an example—is the registry of the European Congenital Heart Surgery Association (ECHSA), running for more than 10 years, and that includes independent audits to allow institutional certification.

Typically, the surgeons themselves or locally dedicated persons (database managers) with varying experience and skills manage their own institutional database and, most of the time, there is no local audit or control process defined. One can reasonably suspect

that a critical selection bias is introduced even before the data entry. Consequently, even with the best cleaning and statistical processes, a legitimate doubt regarding the interpretation of the registry data remains. Cardiothoracic surgeons, obviously better than others, are aware of this limitation but remain, at least some of them, only partially motivated to participate in the process of registering. It is clear that an extra effort is required, even if the process is time-consuming and costly. Nevertheless, large registries are currently managed by professionals who are able to periodically deliver detailed reports with instructive information. Importantly, this information is nowadays increasingly relevant and considered for purposes other than only clinical, namely for strategic, political and economical health decisions. Specific registries may be compared with other registries (demographics for example) for non-specialists to draw conclusions to better organize health-care provision and finally to better serve the population. It is therefore a critical duty of each surgeon or clinic to accept the responsibility of providing the most accurate and exhaustive data set they can.

There is extensive literature not only available on the necessity, but also the quality of national and international registries. As the former president of the American College of Cardiology wrote in an Editorial, 'Registries serve a different purpose: at their best, they serve to measure what is happening in the real world of patients irrespective of whether those patients are candidates for the randomized clinical trials or not' [4].

The information currently available from registries is the result of visionary surgeons who initiated the work a few decades ago, and the numerous registry-based reports that have been published in the scientific literature during the last years prove that this effort was worthwhile [5]. It is now our turn to perpetuate or better implement this work in order to provide the next generation of cardiothoracic surgeons with additional, more accurate information that will hopefully help them as well as other care-providers to reach better health-management strategies.

## REFERENCES

- [1] Hickey GL, Grant SW, Cosgriff R, Dimarakis I, Pagano D, Kappetein AP, Bridgewater B. Clinical registries: governance, management, analysis and applications. *Eur J Cardiothorac Surg* 2013;44:605–15.
- [2] Jeremy RW. To register or not—that is the question. The case for collaboration and a national cardiac procedures database. *Heart Lung Circ* 2011; 20:1–2.
- [3] Ryan TJ. Large cardiac registries: the path to higher quality and lower costs in our healthcare system. *Circulation* 2010;121:2612–14.
- [4] Holmes DR. The President's Page. Measuring and other things. *J Am Coll Cardiol* 2011;58:1638–9.
- [5] Edwards FH. The STS database at 20 years: a tribute to Doctor Richard E. Clark. *Ann Thorac Surg* 2010;89:9–10.